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CLERK'S DISTRICT COURT
CENTRAL DIST. OF CALIF.
SANTA ANA

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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

September 2018 Grand Jury

UNITED STATES OF AMERICA,

Plaintiff,

v.

NAM HYUN LEE,
aka "Daniel Lee,"
aka "Daniel Nam Lee,"
aka "Nam Lee,"

Defendant.

SACR18-00226 JVS

I N D I C T M E N T

[18 U.S.C. § 371: Conspiracy;
18 U.S.C. § 545: Importing
Merchandise Contrary to Law; 21
U.S.C. §§ 331(a), 333(a)(2):
Introducing Misbranded Drugs Into
Interstate Commerce; 18 U.S.C.
§ 2: Aiding and Abetting, Causing
an Act to Be Done; 18 U.S.C.
§§ 981(a)(1)(C), 982(a)(2)(B), and
28 U.S.C. § 2461(c): Criminal
Forfeiture]

UNDER SEAL

The Grand Jury charges:

INTRODUCTORY ALLEGATIONS

At all times relevant to this Indictment:

A. THE DEFENDANT

1. Defendant NAM HYUN LEE, also known as ("aka") "Daniel Lee,"
aka "Daniel Nam Lee," aka "Nam Lee" ("LEE"), owned, controlled, and
operated Hasim Distribution, Inc. ("Hasim Distribution") from

1 approximately June 2016 to October 2018, Dalee Supply, Inc. ("Dalee
2 Supply") from approximately October 2016 to October 2018, Rainbow
3 Natural Production, Inc. ("Rainbow Natural Production") from
4 approximately October 2016 to October 2018, and Hasim Enterprise, LLC
5 ("Hasim Enterprise") from approximately January 2017 to October 2018.

6 a. Hasim Distribution was a California corporation
7 registered in June 2016 and located in Buena Park, California.
8 Defendant LEE was the registered Chief Executive Officer, Secretary,
9 Chief Financial Officer, Director, and Agent for Service of Process
10 for Hasim Distribution.

11 b. Dalee Supply was a California corporation registered
12 in October 2016 and located in Buena Park, California. Defendant LEE
13 was the registered Chief Executive Officer, Secretary, Chief
14 Financial Officer, and Director for Dalee Supply.

15 c. Rainbow Natural Production was a California
16 corporation registered in October 2016 and located in Buena Park,
17 California. Defendant LEE was the registered Chief Executive
18 Officer, Secretary, Chief Financial Officer, Director, and Agent for
19 Service of Process for Rainbow Natural Production.

20 d. Hasim Enterprise was a California corporation
21 registered in February 2017 and located in Cypress, California.
22 Defendant LEE was registered as the sole Manager/Member for Hasim
23 Enterprise, and no individual was listed as the Chief Executive
24 Officer.

25 2. Defendant LEE did not possess a valid wholesale drug
26 distribution license, a valid pharmacy license, or a license to
27 prescribe prescription drugs in the State of California.

1 3. Under defendant LEE's direction, Hasim Distribution, Dalee
2 Supply, Rainbow Natural Production, and Hasim Enterprise marketed and
3 distributed male sexual enhancement capsules that contained the
4 undisclosed active pharmaceutical ingredients Tadalafil and
5 Sildenafil. The male sexual enhancement capsules were marketed under
6 a variety of brand names, including, among others, "Rhino 7
7 Platinum," "Rhino 7 Blue," "Rhino Big Horn," "Orgazen 3000," "Orgazen
8 3500," "Rhino 69 Platinum 9000," "libigrow," "Spanish Fly," "Rhino 8
9 8000," "Black Panther," "Black Stallion," "Black Mamba," "Tiger,"
10 "Rhino 9," "Rhino 8," "Rhino 12," and "Dragon 69."

11 B. THE FOOD, DRUG, AND COSMETIC ACT

12 4. The Food and Drug Administration ("FDA") was the federal
13 agency responsible for protecting the health and safety of the
14 American public by enforcing the Food, Drug, and Cosmetic Act, 21
15 U.S.C. § 301 et seq. ("FDCA"). One of the main purposes of the FDCA
16 was to ensure that human drugs sold were safe, effective, and bore
17 labeling containing only true and accurate information. The FDA's
18 responsibilities under the FDCA included regulating the manufacture,
19 labeling, and distribution of all drugs shipped or received in
20 interstate commerce.

21 5. The FDCA defined a "drug" to include "articles intended for
22 use in the diagnosis, cure, mitigation, treatment, or prevention of
23 disease in man," and "articles (other than food) intended to affect
24 the structure or any function of the body of man." 21 U.S.C.
25 § 321(g)(1)(B) and (C).

26 6. A "prescription drug" was any drug which, "because of its
27 toxicity or other potentiality for harmful effect, or the method of
28 its use, or the collateral measures necessary to its use, [was] not

1 safe for use except under the supervision of a practitioner licensed
2 by law to administer such drug"; or any drug that was "limited by an
3 approved application . . . to use under the professional supervision
4 of a practitioner licensed by law to administer such drug." 21
5 U.S.C. § 353(b)(1).

6 7. Under the FDCA, "label" was defined as "a display of
7 written, printed, or graphic matter upon the immediate container of
8 any article." 21 U.S.C. § 321(k). The term "labeling," in turn, was
9 defined as "all labels and other written, printed, or graphic matter
10 (1) upon any article or any of its containers or wrappers, or
11 (2) accompanying such article." 21 U.S.C. § 321(m).

12 8. The FDCA prohibited the introduction, delivery for
13 introduction, or the causing of the introduction or delivery for
14 introduction into interstate commerce of any drug that was
15 misbranded. 21 U.S.C. § 331(a).

16 9. Under the FDCA, a drug was deemed to be "misbranded" if,
17 among other things, its labeling was false or misleading in any
18 particular, 21 U.S.C. § 352(a), or if its labeling failed to bear
19 adequate directions for use, 21 U.S.C. § 352(f)(1). "Adequate
20 directions for use" meant directions under which a layperson could
21 use a drug safely and for the purposes for which it was intended. 21
22 C.F.R. § 201.5.

23 C. THE DRUGS

24 10. "Viagra" was a drug within the meaning of Title 21, United
25 States Code, Section 321(g)(1), and a prescription drug within the
26 meaning of Title 21, United States Code, Section 353(b)(1). Viagra
27 was the trade name for Pfizer, Inc.'s FDA-approved erectile
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1 dysfunction drug containing the active pharmaceutical ingredient
2 Sildenafil.

3 11. "Cialis" was a drug within the meaning of Title 21, United
4 States Code, Section 321(g)(1), and a prescription drug within the
5 meaning of Title 21, United States Code, Section 353(b)(1). Cialis
6 was the trade name for Eli Lilly & Company's FDA-approved erectile
7 dysfunction drug containing the active pharmaceutical ingredient
8 Tadalafil.

9 12. The FDA's approval of Viagra and Cialis was limited to use
10 under the professional supervision of a practitioner licensed by law
11 to administer such drug; therefore, Viagra and Cialis were
12 "prescription" drugs under Title 21, United States Code, Section
13 353(b)(1). Due to toxicity and other potentially harmful effects
14 (e.g., life-threatening drops in blood pressure; loss of vision; loss
15 of hearing; and prolonged, painful erections that result in permanent
16 injury to the penis), drugs similar to Viagra and Cialis were not
17 safe for use except under the supervision of a practitioner licensed
18 by law to administer them, and they were thus prescription drugs as
19 well.

20 13. These Introductory Allegations are incorporated into each
21 count of this Indictment as though fully set forth therein.

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1 COUNT ONE

2 [18 U.S.C. § 371]

3 A. OBJECTS OF THE CONSPIRACY

4 Beginning on a date unknown to the Grand Jury, but at least as
5 early as on or about December 29, 2015, and continuing to a date
6 unknown to the Grand Jury, but at least on or about October 24, 2018,
7 in Orange and Los Angeles Counties, within the Central District of
8 California, and elsewhere, defendant LEE, together with others known
9 and unknown to the Grand Jury, conspired with each other to knowingly
10 and intentionally commit offenses against the United States, namely,
11 fraudulently and knowingly importing and bringing into the United
12 States, and causing to be imported and brought into the United
13 States, certain merchandise contrary to law, in violation of Title
14 18, United States Code, Section 545; and introducing and causing the
15 introduction of misbranded drugs into interstate commerce, with the
16 intent to defraud and mislead, in violation of Title 21, United
17 States Code, Sections 331(a), 333(a)(2).

18 B. MEANS BY WHICH THE OBJECTS OF THE CONSPIRACY WERE TO BE
19 ACCOMPLISHED

20 The objects of the conspiracy were to be accomplished, in
21 substance, as follows:

22 1. Defendant LEE would order wholesale shipments of bulk
23 Tadalafil and Sildenafil from suppliers in China.

24 2. Defendant LEE's suppliers would fail to state the presence
25 of Tadalafil and Sildenafil on the manifests for the shipments and
26 instead state that the packages contained non-controlled substances
27 or other merchandise.

3. Defendant LEE and other co-conspirators would receive the packages containing Tadalafil and Sildenafil from the Chinese suppliers at various business and residential properties under the control of defendant LEE or employees of defendant LEE.

4. Defendant LEE and other co-conspirators would repackage the wholesale quantities of Tadalafil and Sildenafil into smaller quantities and sell them in the form of a capsule as non-prescription herbal male sexual enhancement supplements.

5. Defendant LEE and other co-conspirators would sell the finished capsules to distributors across the United States in packages whose labeling stated that no prescription was necessary and did not disclose the presence of Tadalafil and Sildenafil.

6. Defendant LEE did not seek FDA approval to market these drugs; nor was defendant LEE licensed as a pharmacist in the State of California or otherwise authorized to prescribe or dispense prescription drugs.

C. OVERT ACTS

On or about the following dates, in furtherance of the conspiracy and to accomplish its objects, defendant LEE, and others known and unknown to the Grand Jury, committed various overt acts within the Central District of California, and elsewhere, including, but not limited to, the following:

Defendant LEE and a Co-Conspirator Agree to Mislabel Shipping
Manifests in Order to Pass U.S. Customs

Overt Act No. 1: On or about December 29, 2015, defendant LEE and Co-Conspirator #1 agreed in an email conversation that the product name contained on shipping manifests for packages shipped to

1 defendant LEE from Co-Conspirator #1 containing bulk Tadalafil and
2 Sildenafil would be changed in order to pass U.S. customs undetected.

3 Overt Act No. 2: On or about March 14, 2016, defendant LEE
4 and Co-Conspirator #1 agreed in an email conversation that the
5 product name contained on shipping manifests for packages shipped to
6 defendant LEE containing bulk Tadalafil and Sildenafil would be
7 changed to "Granular Amino Molding Compound" in order to pass customs
8 undetected.

9 Defendant LEE Establishes Corporations and Companies in Order to
10 Manufacture and Sell Misbranded Drugs

11 Overt Act No. 3: On or about June 15, 2016, defendant LEE
12 caused Hasim Distribution to be established as a corporation through
13 which defendant LEE could manufacture and sell misbranded drugs.

14 Overt Act No. 4: On or about October 7, 2016, defendant LEE
15 caused Rainbow Natural Production to be established as a corporation
16 through which defendant LEE could manufacture and sell misbranded
17 drugs.

18 Overt Act No. 5: On or about October 31, 2016, defendant LEE
19 caused Dalee Supply to be established as a corporation through which
20 defendant LEE could manufacture and sell misbranded drugs.

21 Overt Act No. 6: On or about January 11, 2017, defendant LEE
22 caused Hasim Enterprise to be established as a company through which
23 defendant LEE could manufacture and sell misbranded drugs.

24 Defendant LEE Imports Mislabeled Sildenafil and Tadalafil into
25 the United States

26 Overt Act No. 7: In or about November 2016, defendant LEE
27 caused one parcel containing approximately 21.4 kilograms of

1 unlabeled bulk Sildenafil to be imported from China to Gardena,
2 California, which was manifested as a "Sample of Pentaerythritol."

3 Overt Act No. 8: In or about November 2016, defendant LEE
4 caused one parcel containing approximately 25.10 kilograms of
5 unlabeled bulk Tadalafil and approximately 21.55 kilograms of
6 unlabeled bulk Sildenafil to be imported from China to Fullerton,
7 California, which were manifested as "Acrylic Paint."

8 Overt Act No. 9: In or about November 2016, defendant LEE
9 caused one parcel containing approximately 2.05 kilograms of
10 unlabeled bulk Tadalafil to be imported from China to Buena Park,
11 California, which was manifested as "Health Products."

12 Overt Act No. 10: In or about June 2017, defendant LEE caused
13 one parcel containing approximately 1.84 kilograms of unlabeled bulk
14 Tadalafil to be imported from China to Buena Park, California, which
15 was manifested as "Glass Bottles."

16 Defendant LEE Ships Capsules Containing Sildenafil and Tadalafil
17 to Distributors Outside of California

18 Overt Act No. 11: On or about July 27, 2016, defendant LEE
19 shipped approximately 1,200 "Rhino 8 8000" capsules, containing the
20 active pharmaceutical ingredients Tadalafil and Sildenafil, to a
21 distributor in Beaumont, Texas.

22 Overt Act No. 12: On or about July 27, 2016, defendant LEE
23 shipped approximately 1,200 "Rhino 69 9000" capsules, containing the
24 active pharmaceutical ingredient Sildenafil, to a distributor in
25 Beaumont, Texas.

26 Overt Act No. 13: On or about July 28, 2016, defendant LEE
27 shipped approximately 1,200 "Rhino 8 8000" capsules, containing the
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1 active pharmaceutical ingredients Tadalafil and Sildenafil, to a
2 distributor in Beaumont, Texas.

3 Overt Act No. 14: On or about July 28, 2016, defendant LEE
4 shipped approximately 1,200 "Rhino 69 9000" capsules, containing the
5 active pharmaceutical ingredient Sildenafil, to a distributor in
6 Beaumont, Texas.

7 Overt Act No. 15: On or about September 7, 2016, defendant LEE
8 shipped approximately 2,400 "Rhino 69 9000" capsules, containing the
9 active pharmaceutical ingredient Sildenafil, to a distributor in
10 Beaumont, Texas.

11 Overt Act No. 16: On or about October 18, 2016, defendant LEE
12 shipped approximately 1,000 "Rhino 69 9000" capsules, containing the
13 active pharmaceutical ingredient Sildenafil, to a distributor in
14 Baltimore, Maryland.

15 Overt Act No. 17: On or about November 28, 2016, defendant LEE
16 shipped approximately 1,200 "Rhino 69 9000" capsules, containing the
17 active pharmaceutical ingredient Sildenafil, to a distributor in
18 Baltimore, Maryland.

19 Overt Act No. 18: On or about February 21, 2017, defendant LEE
20 shipped approximately 1,000 "Rhino 69 9000" capsules, containing the
21 active pharmaceutical ingredient Sildenafil, to a distributor in
22 Baltimore, Maryland.

23 Defendant LEE Obtains Packaging and Labeling Material for
24 Misbranded Drugs and Submits Labeling Material to the FDA that
25 Fails to Disclose the Presence of Sildenafil

26 Overt Act No. 19: In or about March 2017, defendant LEE
27 obtained approximately 295 cartons of packaging and labeling material
28 to use to sell products such as "Black Panther," "libigrow," "Black

1 Stallion," and "Black Mamba," which were misbranded drugs that did
2 not bear FDA-approved labeling, and were labeled as non-prescription
3 herbal male sexual enhancement supplements.

4 Overt Act No. 20: On or about February 22, 2018, defendant LEE
5 submitted a "Food Export Certification" to the FDA, along with a
6 label for "Rhino 69 Platinum 9000," verifying that all the
7 ingredients in "Rhino 69 Platinum 9000" were "approved by FDA and
8 appear on the Generally Recognized as Safe List, and each product is
9 intended for human consumption and is available for sale in the U.S.
10 without restriction," when in fact "Rhino 69 Platinum 9000" contained
11 the active pharmaceutical ingredient Sildenafil.

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1 COUNTS TWO THROUGH FOUR

2 [18 U.S.C. §§ 545, 2]

3 On or about the following dates, in Orange and Los Angeles
 4 Counties, within the Central District of California, and elsewhere,
 5 defendant LEE fraudulently and knowingly imported and brought into
 6 the United States, and willfully caused to be imported and brought
 7 into the United States, merchandise, that is, unlabeled bulk
 8 Tadalafil and Sildenafil in the following quantities, contrary to
 9 law, by introducing into interstate commerce prescription drugs that
 10 were misbranded in that their labeling lacked adequate directions for
 11 use, contrary to Title 21, United States Code, Sections 331(a),
 12 352(f)(1):

COUNT	DATE	MERCHANDISE	WEIGHT	DESTINATION
TWO	11/17/16	Sildenafil	21.4 kg	Gardena, California
THREE	11/14/16	Tadalafil	2.05 kg	Buena Park, California
FOUR	6/13/17	Tadalafil	1.84 kg	Buena Park, California

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1 COUNTS FIVE THROUGH TWELVE

2 [21 U.S.C. §§ 331(a), 333(a)(2)]

3 On or about the following dates, in Orange and Los Angeles
 4 Counties, within the Central District of California, defendant LEE
 5 introduced, and caused the introduction of, the following drugs into
 6 interstate commerce, with the intent to defraud and mislead, with the
 7 drugs being misbranded pursuant to Title 21, United States Code,
 8 Section 352(a)(1), because the drugs' labeling falsely and
 9 misleadingly stated "no prescription necessary," even though the
 10 drugs were prescription drugs that contained doses of Tadalafil or
 11 Sildenafil, or both, and because none of the labeling disclosed the
 12 presence of the ingredients Tadalafil or Sildenafil, or both, in the
 13 drugs:

COUNT	DATE	PRODUCT	QUANTITY	RECIPIENT'S LOCATION
FIVE	7/27/16	Rhino 8 8000	1,200	Beaumont, Texas
SIX	7/27/16	Rhino 69 9000	1,200	Beaumont, Texas
SEVEN	7/28/16	Rhino 8 8000	1,200	Beaumont, Texas
EIGHT	7/28/16	Rhino 69 9000	1,200	Beaumont, Texas
NINE	9/7/16	Rhino 69 9000	2,400	Beaumont, Texas
TEN	10/18/16	Rhino 69 9000	1,000	Baltimore, Maryland
ELEVEN	11/28/16	Rhino 69 9000	1,200	Baltimore, Maryland
TWELVE	2/21/17	Rhino 69 9000	1,000	Baltimore, Maryland

1 FORFEITURE ALLEGATION

2 [18 U.S.C. §§ 981(a)(1)(C), 982(a)(2)(B), and 28 U.S.C. § 2461(c)]

3 1. Pursuant to Rule 32.2(a) of the Federal Rules of Criminal
4 Procedure, notice is hereby given to defendant NAM HYUN LEE, also
5 known as ("aka") "Daniel Lee," aka "Daniel Nam Lee," aka "Nam Lee"
6 ("LEE"), that the United States will seek forfeiture as part of any
7 sentence in accordance with Title 18, United States Code, Sections
8 981(a)(1)(C) and 982(a)(2)(B), and Title 28, United States Code,
9 Section 2461(c), in the event of the conviction of defendant LEE
10 under any of Counts One through Four of this Indictment. If so
11 convicted, defendant LEE shall forfeit to the United States the
12 following property:

13 (a) All right, title, and interest in any and all
14 property, real or personal, constituting, or derived from, any
15 proceeds obtained, directly or indirectly, as a result of each such
16 offense, including but not limited to the following real property
17 located in the City of Fullerton, County of Orange, State of
18 California, described as the property located at 1515 West Domingo
19 Road, Fullerton, California, with Assessor's Parcel Number 287-071-

20 28. Title to the real property is currently held in the names of
21 defendant LEE's children: Lemuel Lee (40 percent), Yoon Ji Lee (30
22 percent), and Yoon Jung Lee (30 percent), all of whom are siblings,
23 all as tenants in common; and

24 (b) Any and all merchandise introduced into the United
25 States, in violation of Title 18, United States Code, Section 545, or
26 the value thereof.

(c) To the extent such property is not available for forfeiture, a sum of money equal to the total value of the property described in subparagraphs (a) and (b).

4 2. Pursuant to Title 21, United States Code, Section 853(p),
5 as incorporated by Title 18, United States Code, Section 982(b), and
6 Title 28, United States Code, Section 2461(c), defendant LEE shall
7 forfeit substitute property, up to the total value of the property
8 described in the preceding paragraph if, as the result of any act or
9 omission of defendant LEE, the property described in the preceding
10 paragraph, or any portion thereof: (a) cannot be located upon the
11 exercise of due diligence; (b) has been transferred or sold to, or

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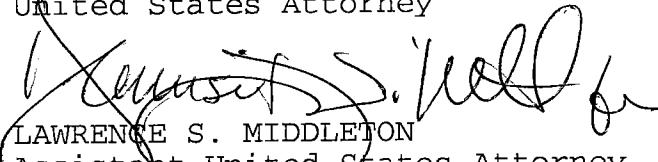
1 deposited with, a third party; (c) has been placed beyond the
2 jurisdiction of the Court; (d) has been substantially diminished in
3 value; or (e) has been commingled with other property that cannot be
4 divided without difficulty.

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Foreperson

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